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| 09/438,104 | 11/10/1999 | ASGEIR SAEBO | CONLINCO-040 | 8881 |

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| EXAMINER |
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JONES, DWAYNE C

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/438,104

Applicant(s)

SAEBO ET AL.

Examiner

Dwayne C Jones

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28NOV2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 7-24 are pending.
2. Claims 7-24 are rejected.

Response to Arguments and Declaration

3. Applicant's arguments and declaration filed November 28, 2003 have been fully considered but they are not persuasive with respect to Cain et al. Applicant's appellant and the Inventor in the declaration made the following arguments. Applicant's appellant argues that neither prior art reference teaches each element of the invention and accordingly the instant claims are not obvious over the prior art rejection of Cain et al. First, applicant alleges that in the declaration of Saebo the methods utilized by Cain et al. were tested and found to produce a variety of isomers other than the desired t10, c12 and c9, t11 isomers. Second, applicant suggests that Mr. Saebo explains why the formation of the 8,10 and 11,13 isomers is a necessary result of the process employed by Cain et al. Third, the formation of the 8,10 and 11,13 isomers occurs by a process known as thermal sigmatropic rearrangement, accordingly applicant argues that the compositions of Cain et al. necessarily contained 8,10 and 11,13 isomers.

4. Applicant alleges that in the declaration of Saebo the methods utilized by Cain et al. were tested and found to produce a variety of isomers other than the desired t10, c12 and c9, t11 isomers. Importantly, it is first noted that the instantly filed claims are only directed to an isomerized conjugated linoleic acid composition that are comprised

of at least 50% "9,11-octadecadienoic acid and 10,12-octadecadienoic acid" with less than 1% of "11,13-octadecadienoic acid and 8,10-octadecadienoic acid" expressed as peak area percentages. For these reasons, the prior art reference of Cain et al. do in fact teach of conjugated linoleic acid (CLA), that has 91.8% of CLA, which is further broken down into 49.7% was the 9,11-isomer and 50.3% was the 10,12-isomer, (see page 11, lines 14-17). Because the instant claims do not distinguish particular geometric isomers of linoleic acid the instant claims are not limited to any particular geometric isomers, and so the arguments regarding the Saebo declaration are not germane to the instantly filed claims. Furthermore, applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310. Accordingly, these claims are open-ended and thus do not rule of the presence of other components or isomers, which would clearly embrace other isomers of CLA.

5. Second, applicant suggests that Mr. Saebo explains why the formation of the 8,10 and 11,13 isomers is a necessary result of the process employed by Cain et al. In fact, the declaration alleges that the t8, c10 isomer co-elutes with the c9, t11 isomer, but almost always occurs in a one to one proportion. However, the results of declaration even list the t10, c12 CLA as 40.35% peak area and c9, t11 CLA along with t8, c10 CLA as 42.84% peak area. Cain et al. once again render the instant invention obvious in view of these peak area percentages that contain both 9,11-octadecadienoic acid and

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10,12-octadecadienoic acid. In addition, the declaration states that the t8, c10 isomer co-elutes with the c9, t11 isomer, but almost always occurs in a one to one proportion. Even assuming arguendo that there is an alleged one-to-one proportion of the c9, t11 CLA to t8, C10 CLA, if the total peak area percentage of the 42.84% was divided by 2 there, still would remain 21.42% c9, t11 CLA present. By adding this alleged remaining 21.42% c9, t11 CLA along with the 40.35% peak area of the t10, c12 CLA, there would be a total of 61.77% present, which exceeds the 50% threshold of peak area percentage. Moreover, even applicant acknowledges that there is ambiguity with the co-elution between t8, c10 isomer and the c9, t11 isomer of CLA with the phrase, "but almost always occurs in a one to one proportion." Clearly, this admission allows for variances with the co-elution of these isomers that could very well give different ratios of the isomers and thus fall within the instantly claimed ranges.

6. In addition, Cain et al. specifically state that of the eight geometric isomers of CLA the isomers of c9, t11 and t10, c12 are the most abundant with about equal concentrations. Cain et al. provide motivation to the skilled artisan to decrease the production of the isomers, which includes 11,13-octadecadienoic acid and 8,10-octadecadienoic acid, and even trans-trans-octadecadienoic acid, with the following statement that the, "two most abundant isomers [c9, t11 and t10, c12] are responsible for the beneficial effects of the compositions containing CLA's, (see page 1, lines 8-11 and 20-25).

7. Third, the formation of the 8,10 and 11,13 isomers occurs by a process known as thermal sigmatropic rearrangement, accordingly applicant argues that the compositions

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of Cain et al. necessarily contained 8,10 and 11,13 isomers. Sigmatropic reactions are well known in the art as reactions that are controlled by molecular orbital symmetry characteristics. In addition, these reactions are often referred to as pericyclic reactions since they occur through cyclic transition states, (see Solomons 1080-1092). In particular, sigmatropic reactions involve a concerted reorganization of electrons during which a group attached by a sigma (σ) bond migrates to a more distant terminus of an adjacent π -electron system, (see Carey, pages 609-613). These pericyclic reactions are governed by the Woodward-Hoffmann Rules, such as certain paths are said to be symmetry allowed while others are referred to be symmetry forbidden. An additional rule requires that these pericyclic reactions have energies of activation that require heat or even photochemical energy for initiation to occur, (see Solomons, pages 1080-1092). With these well known Woodward-Hoffmann Rules, one skilled in the art is provided with the motivation to decrease the thermal energy (heat) of a reaction in order to decrease the generation of other geometric isomers of CLA. For these reasons, it would have been obvious to the skilled artisan to decrease the temperatures in order to control the production of the sigmatropic products, namely the 8,10- and 11,13-octadecadienoic acid isomers.

8. Applicant further alleges that because Cain et al. do not describe the presence of the isomers, namely the 8,10 and 11,13 isomers, in this composition, the only reasonable conclusion is that they did not analyze for these isomers. This allegation is completely speculative. In fact, the skilled artisan is specifically provided with clear motivation to decrease the products of other geometric isomers, since the c9, t11 and

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t10, c12 are responsible for the beneficial effects of the CLA compositions, (Cain et al., page 1, lines 8-11 and 20-25).

Information Disclosure Statement

9. It is respectfully requested any documents, in particular the two references presented in the response of November 28, 2003, that are furnished to the Office by listed on an information disclosure statement to ensure that they are properly reviewed and considered.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 7-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, does not reasonably provide enablement for other 9,11 and 10,12 isomers of octadecadienoic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the

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predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The instant invention is directed to compositions of isomerized conjugated linoleic acids that are comprised of at least 50% "9,11-octadecadienoic acid and 10,12-octadecadienoic acid" with less than 1% of "11,13-octadecadienoic acid and 8,10-octadecadienoic acid" expressed as peak area percentages.

(2) The state of the prior art

The compounds of the inventions are isomerized conjugated linoleic acids that are comprised of at least 50% 9,11-octadecadienoic acid and 10,12-octadecadienoic acid. However, the prior art does not teach that these all of these geometric isomers are biologically effective, see Cain et al. page 1.

(3) The relative skill of those in the art

The relative skill of those in the art of food products and nutraceuticals is high.

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(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839, 192 USPQ 95, 105 (M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re Fischer, 427 F.2d 833, 839, 166 USPQ 10, 24 (CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5 (BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of compositions of adrenocorticotrophic hormones was unpredictable art); In re Wright, 999 F.2d 1557, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of all CLA's prior to filing of the instant invention was an unpredictable art.

(5) The breadth of the claims

The instant claims are very broad. For instance, claims 7, 10, 13, 16, 19, and 22 are directed to the various types of geometric isomers of CLA. The breadth of claims was a factor in Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d (Fed. Cir.), cert. Denied, 502 U.S. 856 (1991). In the Amgen case, the patent claims were directed to DNA sequences that encoded amino acid sequences. Because a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function activity of a protein and because the laws of protein folding are in such a primitive state, predicting protein structure (and hence, activity) while knowing only the sequence of the protein is akin to predicting the weather for a date in the future.

(6) The amount of direction or guidance presented

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fischer, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright,

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999 F.2d 1562-63, 27 USPQ2d 1575. In the instant case, given the unpredictability of the physiological or pharmaceutical activity of all CLA compounds to be effective as food products is insufficient for enablement. The specification provides no guidance, in the way of enablement for all CLAs other than c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

As stated above, the specification discloses all CLAs of other 9,11 and 10,12 isomers of octadecadienoic acid. However, the instant specification only has enablement for c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, see page 5, page 15, Example 1 of the instant specification.

(8) The quantity of experimentation necessary

The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 858 F.2d 737, 8 USPQ2d 1404 (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all of the CLAs of other 9,11 and 10,12 isomers of octadecadienoic acid that would be enabled in this specification.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. The rejection of claims 7-24 under 35 U.S.C. 103(a) as being unpatentable over Cain et al. of WO 97/18320 is maintained and repeated. Cain et al. teach of compositions of conjugated linoleic acid that are used in food products for both animals and humans, (see page 1). Cain et al. teach of a 91.8% conjugated linoleic acid product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer, (see Example 1). In addition, Cain et al. teach of alky esters of these conjugated linoleic acids (see Examples 1 and 3) as well as conjugated linoleic acid triglycerides, (see Example 8). Cain et al. also teach of utilizing the characterization method of HPLC as well as GC (see Example 8). Although Cain et al. do not specifically discuss peak area percentages of the isomers of 11,13-octadecadienoic and 8,10-octadecadienoic acid, it would have been obvious to one having ordinary skill in the art that these isomers would be less than 1% of a peak area because Cain et al. teach of a conjugated linoleic acid composition product of which 49.7% was the cis 9, trans 11-isomer and 50.3 % was the trans 10, cis 12-isomer. Accordingly, Cain et al. teach of a composition which contains a total of 100 % of both the isomers of cis 9, trans 11-isomer and which would obviously exclude any other isomers, including but not limited to 11,13-octadecadienoic and 8,10-octadecadienoic acid. In addition, Cain et al. teach of utilizing the characterization method of HPLC as well as GC, which are known to present data results of analyzed products as percentages based on peak areas. Accordingly, it would have been obvious to one having ordinary skill in the art to express the isomers of conjugated linoleic acid as peak area percentages especially when the

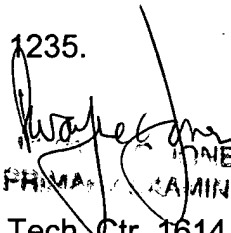
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prior art reference of Cain et al. teach of using the characterization techniques of HPLC and GC, (see the Examples of Cain et al.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. C. JONES
PRIMA EXAMINER
Tech. Ctr. 1614
February 7, 2004